

REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the amendment, remarks and attachments herewith, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 22-49 are pending. Claims 32 and 45-47 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are patentably distinct from the documents cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE REJECTIONS UNDER §112, SECOND PARAGRAPH, ARE OVERCOME

Claims 32 and 45-47 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is traversed.

The amended recitations in claims 32 and 45-47, made without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, have rendered the instant rejection moot.

Consequently, the Section 112, second paragraph, rejection should be reconsidered and withdrawn; and, such relief is respectfully requested.

III. THE REJECTIONS UNDER §112, FIRST PARAGRAPH, ARE OVERCOME

Claims 22, 23, 28, 31-36 and 48-49 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing non-enabling subject matter. The Office Action contends that only limited forms of formula (I) have been shown to be effective for the claimed control, but not for all compounds or compound groups. Applicants respectfully disagree.

It is respectfully reasserted that the instant invention is clearly enabled because a skilled artisan would readily understand that the claimed compounds must have the ability to eradicate fleas in domestic or accommodation premises. Further, the Examiner is directed to pages 11-13 of the application which discuss the efficacy of combining other parasitocides with the compounds of formula (I) or (II). Predictability in the art did exist at the time of filing and, coupled with the knowledge of a skilled artisan and the guidance of the present application, there is sufficient evidence that Applicants' disclosure does satisfy the enablement requirement.

Furthermore, phenylpyrazoles are a class of insecticides which possess excellent insecticidal activity against insect pests including blood-sucking pests such as ticks, and fleas etc., which are parasites on animals. Phenylpyrazoles are within the class of compounds known as arylheterocycles. This class of agents kills insects by acting on the gamma-butyric acid (GABA) receptor of invertebrates (*See, e.g.,* Bloomquist, *Ann Rev Entomol*, 41:163-90 (1996) (Abstract attached).

The compounds according to formula (I) are very lipophilic and of high vapor pressure (low volatility). Thus, the compounds have a very high affinity for the sebum and are taken up by the sebaceous glands. Indeed, Cochet et al., *Eur J Drug Metab Pharmacokinet* 22(3):211-6 (1997) (copy of Abstract attached) showed that fipronil, an exemplary compound within formula (I), indeed is taken up in the sebaceous glands (and epithelial layers) of animals. Since the compounds of formula (I) are very lipophilic and of high vapor pressure (low volatility) there is no reason to doubt that they too, like fipronil, will be taken up in the sebaceous glands (and epithelial layers) of animals.

Hainzl et al., *PNAS USA* 93(23):1276407 (1996) showed that desulfinylfipronil, the trifluoromethylpyrazole derivative of fipronil, is formed when fipronil is used as a plant insecticide (exposed to sunlight). Hainzl et al. 1996 also showed that desulfinylfipronil, the trifluoromethylpyrazole derivative of fipronil, a phenylpyrazole related to fipronil, has high neuroactivity, like fipronil and suggests that desulfinylfipronil can be a significant contributor to the effectiveness of fipronil as an insecticide for crop protection.

Since fipronil derivatives have neurotoxicity, there is no reason to doubt that compounds of formula (I) will likewise be active against fleas and ticks. Hainzl et al. 1996 states that the trifluoromethylsulfinyl moiety of fipronil is "presumably important in its outstanding performance." In this regard, note that in formula (I) compounds, it is preferred that R₂ be

$S(O)_nR_3$ with R_3 being preferably ethyl or haloalkyl (application at page 4), with particular mention being made of formula (I) compounds wherein $n=0$ and R_3 is CF_3 , and formula (I) compounds wherein $n=1$ and R_3 is ethyl (application at page 4). Further page 5 teaches a preferred class of compounds of formula (I) consists of those wherein R_1 is CN, R_3 is haloalkyl, R_4 is NH_2 , R_{11} and R_{12} are, independently of each other, is a halogen atom, and/or R_{13} is haloalkyl.

Thus the skilled artisan, looking to the specification, is directed to compounds of formula (I) having the trifluoromethylsulfinyl moiety of fipronil which is recognized as "important in its outstanding performance", as well as to formula (I) compounds wherein $n=0$ and R_3 is CF_3 or wherein $n=1$ and R_3 is ethyl (and thus R_2 is $S(O)_nR_3$), and compounds of formula (I) wherein R_1 is CN, R_3 is haloalkyl, R_4 is NH_2 , R_{11} and R_{12} are, independently of each other, is a halogen atom, and R_{13} is haloalkyl (and thus R_2 is $S(O)_nR_3$), such that the specification provides a great deal of guidance, in addition to the Examples as to compounds within formula (I) that are especially useful in the practice of the invention; and, the skilled artisan would likely initially select those preferred compounds in any screening.

Further still, Hainzl et al. 1996 was followed by Hainzl et al., Chem Res Toxicol 11(12):1529-35 (1998), wherein the authors showed that phenylpyrazoles related to fipronil, such as desulfinyl fipronil and fipronil sulfone, indeed acted on the GABA receptor of insects. Thus those compounds too will act as insecticides, like fipronil.

Accordingly, it is clear that compounds in addition to fipronil, within formula (I), act as insecticides; and, there is no reason to doubt that a sufficient number of compounds within formula (I) function to kill fleas and ticks. Also, it is clear that the specification provides guidance as to compounds within formula (I) which should perform like fipronil (especially considering literature such as Hainzl et al. 1996 and Hainzl et al. 1998).

In addition, given that the insecticide mode of action of fipronil and of phenylpyrazoles within formula (I) is known (namely acting on the GABA receptor by blocking the chloride channel), no undue experimentation is required to test the insecticidal action of any compound within formula (I): One need only test compounds for this mode of action, or neuroactivity (or neurotoxicity), or for IC_{50} ; e.g., as in Hainzl et al. 1996 and Hainzl et al. 1998.

Accordingly, it has been shown that a sufficient number of compounds within the generic formula of the claims function as claimed—by diffusing over the mammal's body to thereby kill fleas when they bite.

The Office Action asserts that there is no expectation of eradication from the premises. It is respectfully submitted that the Office Action fails to appreciate fleas, and their life cycle.

Even more than humans, fleas are faithful creatures. While human-to-human marriages may have a high rate of failure, i.e., divorce, fleas are rather faithful to their mammalian hosts.

Indeed, in Dryden, *Veterinary Parasitology*, 34:117-22 (1989) (copy enclosed), it was shown that 80.0% of female fleas and 66.7% of male fleas remained associated with their host, leading to the "apparent" conclusion of a "permanent association" of the flea with its host.

Thus, as stated in Brody, "As Summer Nears, The Mighty Flea Reports for Duty," New York Times, Tuesday, June 1, 1999 (copy enclosed), "one Cornell professor, upon returning from vacation, would send his dog in first for a few hours to feed the resident fleas before he entered the home."

Simply, once a flea selects its host, even if dislodged therefrom, the flea generally remains faithful to feeding from that host, and, a flea tends to stay associated with its host.

Further, Dryden et al., *Veterinary Parasitology*, 52:1-19 (1994), while addressing insecticides unrelated to the present invention, e.g., methoprene (such that Dryden et al., either individually or in any combination, fails to teach or suggest the present invention), at 11-12 indicates that fleas must feed on their host for systemic products to kill; and, that if "on-animal" products are applied at appropriate intervals, future generations will be prevented by killing before egg production is initiated (as the blood meal is required for reproduction, and it is from reproduction—shedding of eggs into premises—that results in the infestation of the premises).

Thus, Brody, in 1999 reports:

Dr. Dryden showed that once they sink into a blood supply, adult fleas hang on to the animal for life. Even though the other stages of a flea's life are spent off the animal, the new flea control products, which include...skin penetrating insecticides that are used only on the infested animal, are able to interrupt the flea's life cycle by killing off adult fleas when they seek their blood meal [and thus treat the animal's environment].

Accordingly, compounds of the present invention, when topically administered to a localized region, diffuse through the mammal's sebaceous glands and remain there for a prolonged period of time, whereby a flea is killed by biting the animal: the life cycle of the flea is, thus, interrupted. The adult pre-reproduction blood meal becomes a fatal last supper, preventing egg shedding and premises infestation. The larvae blood meal becomes a pre-maturity death sentence. The present invention is confirmed by the post-filing New York Times article of Brody.

Therefore, the class of compounds of the claims functions as recited in the claims, and the claims are limited to only those compounds in the generic formula that so function (to diffuse through the sebaceous glands); and, the effect is that the bite of the flea eradicates the fleas from premises by effectively disrupting the flea life cycle.

Thus, it is respectfully submitted that the assertion in the Office Action that the claims are not enabled is incorrect.

Consequently, the Section 112, first paragraph, rejection should be reconsidered and withdrawn; and, such relief is respectfully requested.

IV. THE DOUBLE PATENTING REJECTION BASED ON U.S. PATENT NO. 6,096,329 IS OVERCOME

Claim 45 was rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 49-68 of U.S. Patent No. 6,096,329 (the "329 patent"). The rejection is respectfully traversed.

The claims of the '329 patent relate to a method for controlling fleas and ticks on mammals by locally applying a synergistically effective amount of a spot-on composition. Hence, the '329 patent relates to a method of controlling fleas and ticks on mammals and not necessarily, *inter alia*, a method for eradication of fleas in domestic or accommodation premises.

The claims of the instant invention, by contrast, are directed to a method for the eradication of fleas in domestic or accommodation premises of a domestic or laboratory mammal, comprising topically applying, at least monthly, to a localized region having a surface area between 5 and 10 cm² on the domestic or laboratory mammal, a parasitically effective amount of a spot-on topical preparation comprising a veterinarily acceptable vehicle and a compound of the formula I, wherein a second parasiticide is selected from the group consisting

C

of those compounds mimicking juvenile hormones and chitin synthesis inhibitors, which are patentably distinct from the claims of the '329 patent. Thus, even assuming, *arguendo*, the claims of the present invention are encompassed by claims of the '329 patent, or *vice versa*, that does not mean that there is automatically double patenting. The Examiner is respectfully reminded that a species (or subgenus) may be patentably distinct from a genus. *See e.g., In re Baird*, 29 U.S.P.Q.2d 1550, 1551 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."). *See also, In re Jones*, 21 U.S.P.Q.2d 1941, 1943 (Fed. Cir. 1992) (rejecting Commissioner's argument that "regardless [] how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it").

Further, a finding of obviousness-type double patenting turns on whether the invention defined in a **claim** in the application in issue is an obvious variation of the invention defined in a **claim** in a prior patent. *See, e.g., In re Berg*, 46 U.S.P.Q.2d, 1226 (Fed. Cir. 1998). In order for an obviousness-type double patenting rejection to stand, the Examiner must show that the claims in issue are obvious **based solely on the claims in the prior patent**; the disclosure in the prior patent may not be used as prior art. *See also In re Kaplan*, 229 U.S.P.Q. 678, 683 (Fed. Cir. 1986). Furthermore, any obvious-type double patenting rejection should make clear: (1) the differences defined by the conflicting claims; and, (2) the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent. *See id.*

The claims of the '329 patent relate to a method for controlling fleas and ticks on mammals by locally applying a synergistically effective amount of a spot-on composition. As noted above, however, the claims of the instant invention are directed to, *inter alia*, a method for the eradication of fleas in domestic or accommodation premises of a domestic or laboratory mammal, comprising topically applying, at least monthly, to a localized region having a surface area between 5 and 10 cm² on the domestic or laboratory mammal, a parasitically effective amount of a spot-on topical preparation comprising a veterinarily acceptable vehicle and a compound of the formula I, wherein a second parasiticide is selected from the group consisting of those compounds mimicking juvenile hormones and chitin synthesis inhibitors.

By contrast, there is nothing in the claims of the '329 patent that teaches or suggests, *inter alia*, a method for the eradication of fleas in domestic or accommodation premises of a

domestic or laboratory mammal, comprising topically applying, at least monthly, to a localized region having a surface area between 5 and 10 cm² on the domestic or laboratory mammal, a parasitically effective amount of a spot-on topical preparation comprising a veterinarily acceptable vehicle and a compound of the formula I, wherein a second parasiticide is selected from the group consisting of those compounds mimicking juvenile hormones and chitin synthesis inhibitors. The issue outlined in the Office Action concerning the conflicting claims encompassing the instant claims is irrelevant in view of the Federal Circuit precedent. *See also In re Kaplan* 229 U.S.P.Q. 678, 681, 683 (Fed. Cir. 1986) (fact that claims of patent and application may encompass each other not controlling for double patenting “This commonplace situation [of one patent dominating another] is not *per se* double patenting”). Without the requisite suggestion and motivation in the claims of the ‘384 patent, the obviousness-type double patenting rejection simply cannot stand.

Finally, the Federal Circuit applies a two-way analysis to determine whether an obviousness-type double patenting rejection should stand: “the test is whether the subject matter of the claims of the patent sought to be invalidated would have been obvious from the subject matter of the claims of the [application], and vice versa.” *Carman Industries v. Wahl*, 724 F.2d 932, 940 (Fed. Cir. 1983). Clearly such a test fails in the instant situation because the subject matter of the claims of the ‘329 patent would not have been obvious from the subject matter of the instant claims. Simply, a method for controlling fleas and ticks on mammals over a long duration of time, while possibly encompassing some methods for the eradication of fleas in accommodation premises of a domestic or laboratory mammal, does not *per se* teach or suggest methods for the eradication of fleas in domestic or accommodation premises of a domestic or laboratory mammal, comprising topically applying, at least monthly, to a localized region having a surface area between 5 and 10 cm² on the domestic or laboratory mammal, a parasitically effective amount of a spot-on topical preparation comprising a veterinarily acceptable vehicle and a compound of the formula I, wherein a second parasiticide is selected from the group consisting of those compounds mimicking juvenile hormones and chitin synthesis inhibitors.

Accordingly, while there may be overlap, this does not mean that there is double patenting as double patenting requires two-way obviousness: i.e., the claims of the instant application must be obvious from the ‘329 patent claims, and the ‘329 patent claims must be obvious from the claims of the instant application. Such two-way obviousness has not been

demonstrated. Ergo, the double patenting rejection cannot stand, and should be reconsidered and withdrawn.

Accordingly, reconsideration and withdrawal of the double patenting rejection based on the '329 patent are respectfully requested.

V. THE REJECTIONS UNDER §102 ARE OVERCOME

Claims 22, 23, 28, 31-36, 38-39, 42, 43 and 49 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Frontline brochure ("Frontline"); and, claims 22, 23 and 43-47 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Sirinyan, DE 4443888 ("DE '888"). These rejections will be addressed collectively and are respectfully traversed. None of the cited documents anticipate the instant invention.

Applicants' invention is directed to, *inter alia*, a method for the eradication of fleas in domestic or accommodation premises of a domestic or laboratory mammal, comprising topically applying, at least monthly to a localized region having a surface area between 5 and 10 cm² on the domestic or laboratory mammal, a parasitically effective amount of a spot-on topical preparation comprising a veterinarily acceptable vehicle and a compound of Formula I or Formula II, wherein the preparation is so applied to the mammal, through the action of the compound and the vehicle, that the compound diffuses over the mammal's body, and then dries without crystallization and without modifying the mammal's appearance and coat. None of the cited documents disclose, suggest or teach such an invention.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applying the law to the instant facts, the documents relied upon by the Office Action do not disclose, suggest or enable Applicants' invention. Firstly, none of the documents contain all of the elements of the instant claims. Claim 22 provides for a method of, *inter alia*, eradicating

fleas in domestic or accommodation premises by applying a parasitically effective amount of a spot-on topical preparation comprising a veterinarily acceptable vehicle and a compound of Formula I or Formula II. None of the cited documents read on the instant claims. None of the cited documents teaches or suggests eradicating fleas from a premises; and, even the Examiner's Section 112 position refutes this rejection, because in the Section 112 rejection, the Examiner recognizes that the art does not teach or suggest eradicating fleas from the premises by topical application to a mammal. Furthermore, Brody (the above-quoted New York Times article) shows that the present invention was not recognized in the press until 1999; and, it was then hailed in the popular press.

Secondly, none of the cited documents enable Applicants' invention, which provides for a method of, *inter alia*, eradicating fleas in domestic or accommodation premises by applying a parasitically effective amount of a spot-on topical preparation comprising a veterinarily acceptable vehicle and a compound of Formula I or Formula II. For these reasons alone, the Section 102 rejections should be obviated.

Specifically, Frontline relates to "convenient, spot treatment for fast acting, long lasting control of fleas and ticks" on dogs. DE '888 relates to use of imidacloprid and possible combination with other parasitocides such as IGRs. Example 1 of DE '888 relates to a dermal formulation on dogs. Daily treatment is suggested, but it is believed that periodical infestation with fleas was conducted by putting the fleas directly onto the animal (*see* page 15, lines 45-46). Further still, Dryden et al. 1994 (cited herein *supra*), at 11, directs the artisan towards premises (environmental) application, indicating that the art heretofore did not recognize environmental treatment or eradication via treatment of the mammal as herein claimed.

Moreover, there is no indication in DE '888 whether the animals were kept in any specific premises. Indeed, there is no disclosure, teaching or even a suggestion that the treatment of the dogs also eradicated fleas in the premises. Neither document, therefore discloses, suggests or enables, *inter alia*, a method for the eradication of fleas in domestic or accommodation premises of a domestic or laboratory mammal, comprising topically applying, at least monthly, to a localized region having a surface area between 5 and 10 cm² on the domestic or laboratory mammal, a parasitically effective amount of a spot-on topical preparation comprising a veterinarily acceptable vehicle and a compound of Formula I, or optionally of a compound of Formula II, wherein, when the preparation is so applied to the mammal, through the action of the

compound and the vehicle, the compound diffuses over the mammal's body, and then dries without crystallization and without modifying the mammal's appearance and coat.

The Examiner appears to be implying that the relied-upon documents inherently disclose the instant invention. It is not enough, however, for an examiner to contend that the compounds or methods in the relied-upon documents "inherently" speak to the instantly claimed invention. It is, in fact, not enough to simply "speculate," as the Examiner does, that the relied-upon documents "inherently" speak to the instantly claimed invention. Speculation is not enough. *See Rapoport v. Dement*, 59 U.S.P.Q.2d 1215 (Fed. Cir. 2001). The documents must disclose or suggest the properties for inherency to attach. According to *In re Rijckaert*, 9 F.3d 1531, 1957 (Fed. Cir. 1993), "such a retrospective view of inherency is not a substitute for some teaching or suggestion[.]" The Federal Circuit is clear that "inherency ...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency]." *Continental Can Company v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991), *citing to In re Oelrich*, 666 F.2d 578, 581-582 (C.C.P.A. 1981). Indeed, "before a reference can be found to disclose a feature by virtue of its inherency, one of ordinary skill in the art viewing the reference must understand that the unmentioned feature at issue is *necessarily* present in the reference." *SGS-Thomson Microelectronics, Inc. v. International Rectifier Corporation*, 31 F.3d 1177 (Fed. Cir. 1994) (emphasis in original). Applying the law to the instant facts, none of the documents cited in the Final Office Action inherently teach, disclose or suggest Applicants' invention.

Indeed, the Examiner has not shown that the Frontline spray functions as the spot-on of the instant claims on the animal (e.g., diffusion over the entire animal) or that the skilled artisan would have recognized treatment of the premises and eradication of the fleas resulting therefrom (as the skilled artisan would not have recognized the instant invention from the prior art).

In this respect, too, the Examiner is respectfully reminded that the present claims are method claims; and the preamble recitation of the present claims must be fully considered in assessing patentability. *See, e.g., Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 7 U.S.P.Q.2d 1315 (Fed. Cir. 1988); *In re Tuominen*, 671 F.2d 1359, 213 U.S.P.Q. 89 (C.C.P.A. 1982); *In re Bulloch et al.*, 604 F.2d 1362, 203 U.S.P.Q. 171 (C.C.P.A. 1979); *In re Szajna et al.*, 422 F.2d 443, 164 U.S.P.Q. 632 (C.C.P.A. 1970); *In re Walles et al.*, 366 F.2d 786, 151 U.S.P.Q. 185 (C.C.P.A. 1966); *Smith v. Bousquet*, 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940); *Ex*

C

parte Varga, 189 U.S.P.Q. 204 (P.O.B.A. 1973); *see also Kropa v. Robie et al.*, 187 F.2d 150, 88 U.S.P.Q. 478 (C.C.P.A. 1951). When the preamble of the present claims is fully considered, it is clear that the art fails to teach or suggest the instant invention.

Consequently, reconsideration and withdrawal of the Section 102 rejections are believed to be in order and such action is respectfully requested.

VI. THE REJECTIONS UNDER §103 ARE OVERCOME

Claims 22, 23, 28, 21-36, 38-43, 48 and 49 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Frontline (TOP SPOT) in view of Meo '96 and Postal et al. '95; claims 22, 23 and 43-47 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Sirinyan et al. DE 4443888; claims 22, 23 and 43-47 were rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Sirinyan et al. DE 4443888 in view of Mencke et al. U.S. Patent No. 5,912,295; claims 22, 23, 28, 31-36 and 43-49 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Senbo U.S. Patent No. 5,567,429 in view of Mencke et al. U.S. Patent No. 5,912,295; and claims 22, 23, 28-36 and 38-49 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Steller et al. U.S. Patent No. 5,939,441 in view of Mizutan WO96/16544 and Hatton et al. EP 0295117 (with respect to this last ground for rejection, although the Final Office Action recites that these claims are allegedly "anticipated" by Stellar "in view of" Mizutan and Hatton, as an anticipatory rejection cannot, as a matter of law, be based on a combination of references, it is believed that the Examiner intended the rejection to be one of obviousness under 103(a)). These rejections will be addressed collectively and are all respectfully traversed. None of the numerous documents (indeed, nine documents relied upon in five sets of rejections based on alleged obviousness), either alone or in combination, teach, suggest or disclose the present invention.

The remarks addressing the Section 102 rejections, above, are equally applicable here and are incorporated herein by reference. As explained above, Applicants' invention is directed to, *inter alia*, a method for eradicating fleas in domestic or accommodation premises of a domestic or laboratory mammal, comprising topically applying, at least monthly to a localized region having a surface area between 5 and 10 cm² on the domestic or laboratory mammal, a parasitically effective amount of a spot-on topical preparation comprising a veterinarily acceptable vehicle and a compound of Formula I or Formula II.

None of the nine cited documents, either alone or in combination, disclose such a method, nor suggest or motivate a skilled artisan to practice such a method. In this respect, too, the Examiner is respectfully reminded again that the present claims are method claims; and the preamble recitation of the present claims must be fully considered in assessing patentability. *See, e.g., Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 7 U.S.P.Q.2d 1315 (Fed. Cir. 1988); *In re Tuominen*, 671, F.2d 1359, 213 U.S.P.Q. 89 (C.C.P.A. 1982); *In re Bulloch et al.*, 604 F.2d 1362, 203 U.S.P.Q. 171 (C.C.P.A. 1979); *In re Szajna et al.*, 422 F.2d 443, 164 U.S.P.Q. 632 (C.C.P.A. 1970); *In re Walles et al.*, 366 F.2d 786, 151 U.S.P.Q. 185 (C.C.P.A. 1966); *Smith v. Bousquet*, 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940); *Ex parte Varga*, 189 U.S.P.Q. 204 (P.O.B.A. 1973); *see also Kropa v. Robie et al.*, 187 F.2d 150, 88 U.S.P.Q. 478 (C.C.P.A. 1951). When the preamble of the present claims is fully considered, it is clear that the art fails to teach or suggest the instant invention.

Further, none of the documents suggest, teach or motivate a skilled artisan to practice the instant invention. The Examiner is respectfully reminded of the case law; namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

One of the unique features of Applicants' invention is that fleas are eradicated from domestic or accommodation premises by applying the instant formulation as a spot-on onto the domestic or laboratory mammal. None of the documents cited in the Final Office Action teach, recite, disclose or inherently suggest such an invention. Specifically, none of the cited documents teaches or suggests eradicating fleas from a premises; and, even the Examiner's Section 112 position refutes this rejection, because in the Section 112 rejection, the Examiner

recognizes that the art does not teach or suggest eradicating fleas from the premises by topical application to a mammal. Further still, the Brody New York Times article shows that the present invention was not recognized in the press until 1999, thereby again leading to the conclusion that the present invention cannot be rendered obvious by any of the documents relied upon by the Final Office Action, either alone or in combination.

Indeed, it cannot be argued that any of the documents inherently achieves flea eradication of the premises. It is not enough for one to contend that the compounds or methods in the relied-upon documents “inherently” speak to the instantly claimed invention. It is, in fact, not enough to simply “speculate,” as the Examiner does, that the relied-upon documents “inherently” speak to the instantly claimed invention. Speculation is not enough. *See Rapoport v. Dement*, 59 U.S.P.Q.2d 1215 (Fed. Cir. 2001). The documents must disclose or suggest the properties for inherency to attach. According to *In re Rijckaert*, 9 F.3d 1531, 1957 (Fed. Cir. 1993), “such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection.” The Federal Circuit is clear that “inherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency].” *Continental Can Company v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991), *citing to In re Oelrich*, 666 F.2d 578, 581-582 (C.C.P.A. 1981). Indeed, “before a reference can be found to disclose a feature by virtue of its inherency, one of ordinary skill in the art viewing the reference must understand that the unmentioned feature at issue is *necessarily* present in the reference.” *SGS-Thomson Microelectronics, Inc. v. International Rectifier Corporation*, 31 F.3d 1177 (Fed. Cir. 1994) (emphasis in original). Applying the law to the instant facts, none of the documents cited in the Office Action inherently teach, disclose or suggest Applicants’ invention. That is, none of the documents inherently teach, disclose or suggest eradication of fleas in domestic or accommodation premises by the spot-on application of the instant formulations on the mammal. Thus, inherency cannot attach.

Consequently, reconsideration and withdrawal of the rejections are believed to be in order and such action is respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner and his SPE is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

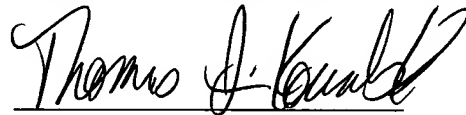
CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By:



Thomas J. Kowalski
Reg. No. 32,147
Samuel H. Megerditchian
Reg. No. 45,678
(212) 588-0800



VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE ABSTRACT:

Method for eradication of fleas in domestic or accommodation premises of a domestic or laboratory mammal.

IN THE SPECIFICATION:

RELATED APPLICATIONS

This application was filed pursuant to 35 U.S.C. § 371 from international application PCT/FR98/00601, filed on March 25, 1998, which, in turn, claims priority to French Application 97/03709, filed on March 26, 1997.

IN THE CLAIMS:

32. (Amended) The method according to claim [1] 22, wherein R_{13} is CF_3 .
45. (Amended) The method according to claim [41] 44, wherein the second parasiticide is selected from the group consisting of those compounds mimicking juvenile hormones and chitin synthesis inhibitors.
46. (Amended) The method according to claim [41] 44, wherein the second parasiticide is an endectocidal parasiticide of macrocyclic lactone type.
47. (Amended) The method according to claim [41] 44, wherein the second parasiticide is selected from the group consisting of avermectins, ivermectin, abamectin, doramectin, moxydectin, milbemycins and derivatives thereof.